

## A bioelectronic assay for PSA activity

### Award Information

#### Agency:

Department of Health and Human Services

#### Branch

n/a

#### Amount:

\$200,628.00

#### Award Year:

2010

#### Program:

SBIR

#### Phase:

Phase I

#### Contract:

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CA156786

#### Solicitation Year:

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#### Solicitation Topic Code:

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#### Solicitation Number:

PHS2010-2

#### Small Business Information

#### OHMX CORPORATION

OHMX CORPORATION, 1801 MAPLE AVE, STE 6143, EVANSTON, IL, 60201

#### Hubzone Owned:

N

#### Socially and Economically Disadvantaged:

N

#### Woman Owned:

N

#### Duns:

199733390

#### Principal Investigator:

DIMITRA GEORGANOPOULOU

(626) 825-6962

DIMITRA@OHMXBIO.COM

#### Business Contact:

DIMITRA GEORGANOPOULOU

(773) 936-1932

dimitra@ohmx.com

#### Research Institution:

n/a

#### Abstract

DESCRIPTION (provided by applicant): Ohmx Corporation is developing integrated point-of-care (POC) bioelectronic sensor technologies for protein biomarkers relevant to cancer diagnosis and risk stratification. The principal goal of this SBIR proposal is to develop an assay for prostate-specific antigen (PSA) proteolytic enzyme activity to improve the early diagnosis and prognosis of prostate cancer. In the United States alone, prostate cancer remains a predominant solid-organ malignancy-192,280 new cases in 2009-and the second leading cause of cancer death among men. It is estimated that one in six men will develop this cancer in their lifetime. Most prostate cancers grow very slowly, but if they spread, they do so rapidly and result in fatality. The indolent nature of early prostate cancer makes it amenable to curative treatment and a suitable disease for early detection strategies. Current screening relies on a digital rectal examination (DRE) and a serum PSA test. When the DRE is normal, serum PSA levels represent the main instrument for biopsy decision to confirm prostate cancer diagnosis. However, an enlarged prostate due to benign prostatic hyperplasia (BPH) also leads to increased concentrations of PSA in serum. Thus, the major problem with screening for serum PSA by immunoassay is the high false positive rate caused by BPH which places a large burden on the healthcare system and leads to unnecessary patient discomfort. In addition, it is not possible to differentiate aggressive cancer that warrants radical treatment from insignificant cancer that would benefit from active surveillance. Recent studies and preliminary data at Ohmx suggest PSA activity levels, rather than mere biomarker presence, may improve the specificity for prostate cancer detection. However, immunoassays do not measure the proteolytic action of PSA and currently no commercial assays exist for quantifying PSA activity. Ohmx proposes to address this need by developing a POC bioelectronic test for PSA activity. The technological innovation behind the Ohmx PSA activity assay is a modified electrode interface of nanostructured elements that translate the enzymatic action of PSA into an amplified electronic signal. The long-term goal of the proposed project is to integrate the Ohmx PSA activity assay into a low-cost diagnostic device for use in the clinic. For Phase I, the specific aims are 1.) To optimize and validate a sensitive and selective electrochemical assay for PSA proteolytic activity, and 2.) To use the Ohmx PSA activity assay to measure PSA enzymatic activity in clinical urine samples. Plans for follow-on Phase II research include prototype sensor fabrication and testing with a larger class of clinical samples to ascertain the positive predictive value of active PSA to discriminate cancer from benign disease. The market for clinical PSA tests is estimated at 450 million and the Ohmx commercialization strategy is to establish a strategic partnership with a major diagnostics company to serve as a distribution partner. PUBLIC HEALTH RELEVANCE: Since the discovery of prostate-specific antigen (PSA) as a biomarker for prostate cancer, there have been countless studies attempting to improve the accuracy of its use for cancer detection to reduce false positives and limit unnecessary surgical intervention. Recent studies and preliminary data at Ohmx suggest that the activity levels of PSA, rather than mere biomarker presence, may improve the specificity for prostate cancer detection. Given that existing commercial PSA assays do not measure enzymatic function, Ohmx Corporation is developing an innovative integrated point-of-care (POC) bioelectronic sensor for PSA activity to ascertain the clinical utility of this important parameter to segregate benign from malignant prostatic disease to allow better-informed treatment decisions.

\* information listed above is at the time of submission.